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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/606,678 | 06/26/2003 | Timothy M. Crowder | 9336-3 | 5316 |

20792 7590 03/04/2005

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

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| EXAMINER |
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TRAN, KHOI H

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| ART UNIT | PAPER NUMBER |
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3651

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,678

Applicant(s)

CROWDER ET AL.

Examiner

Khoi H Tran

Art Unit

3651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 and 65-76 is/are pending in the application.
- 4a) Of the above claim(s) 13, 18, 23, 24, 29-54, 65-73, 75 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17, 19-22, 25-28 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.


Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


KHOI H. TRAN
PRIMARY EXAMINER

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/04, 04/04, 12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant election with traverse of group Group I, Species I (Figure 1A), claims 1-12, 14-17, 19-22, 25-28 and 74 in the response filed on 01/06/2005 is acknowledged. The traversal is on the ground(s) that the invention would required common or non-burdensome search and do not comprise independent and distinct inventions. This is not found persuasive because while there may or may not be overlapping searches for each of the defined inventions, the divergent subject matter contained in the nonelected group(s) or invention(s) would warrant significant additional consideration if addressed on the merits. Additionally, the Examiner remains of the position that the inventions as defined in the previous restriction requirement comprise distinct and independent inventions as discussed in the last Office Action. The requirement is still deemed proper and hereby made Final.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claims 19 and 20, "gas flow path" lacks antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1, 2, 8, 9, 12, 14, 16, 25-28, and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Semenenko 6,296,152.

Semenenko '152 discloses a method for dispensing fine powder from a vibratory hopper into a receiver per claimed invention. Semenenko '152 varies the frequency and amplitude of the vibrating hopper in accordance to the type of powder being discharged. In doing so, Semenenko provides non-linear vibration to the dispensing system.

In regards to claim 74, since Semenenko '152 anticipates all claimed method steps, it is inherent that Semenenko '152 powder dispensing method is applicable in a pharmaceutical environment.

6. Claims 1, 2, 8, 9, 12, 14, 16, 25-28, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Schuller et al. 6,488,181.

Schuller '181 discloses a method for dispensing fine powder from a vibratory hopper into a receiver per claimed invention. Schuller '181 continuously varies the vibrating frequency of the hopper in accordance to a desired metered quantity of powder being discharged. In doing so, Schuller provides non-linear vibration to the dispensing system.

In regards to claim 74, since Schuller '181 anticipates all claimed method steps, it is inherent that Schuller '181 powder dispensing method is applicable in a pharmaceutical environment.

7. Claims 1-3, 8, 9, 12, 14, 16, 25-28, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Pinkas et al. 6,805,175.

Pinkas '175 discloses a method for dispensing pharmaceutical powder from a vibratory hopper into a receiver per claimed invention. Pinkas '175 varies the frequency and amplitude of the vibrating hopper in accordance to the type of powder being discharged. In doing so, Pinkas provides non-linear vibration to the dispensing system. Pinkas '175 synchronizes the dispensing port to open for a predetermined amount of time corresponding to the desired metered flow rate.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4-7, 17, 21, 22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Semenenko 6,296,152.

In regards to claims 4-7, Semenenko '152 discloses all elements per claimed invention. However, it is silent as to the specifics of dispensing the powder in the range of about $10\mu\text{g}$ - $10\text{mg} \pm 10\%$. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to have dispensed about $10\mu\text{g}$ - $10\text{mg} \pm 10\%$ of powder from Semenenko '152 vibratory dispensing hopper, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. In addition, it is obvious that $10\mu\text{g}$ - $10\text{mg} \pm 10\%$ of powder could be dispensed from Semenenko '152 hopper based of user's design.

In regards to claims 10, 11, and 15, Semenenko '152 discloses providing input signals to vary the vibration frequency and amplitude of the hopper according to the type of powder formulation held therein. However, it is silent as to the specifics of deriving said signals from the evaluation of observed frequency space to render frequency distribution data of the mass flow analysis of the dry powder formulation.

Nevertheless, it is obvious well known that in order to provide proper input signals to correctly vary the frequency and amplitude of the vibratory hopper according to the type of powder held therein, analysis of frequency/amplitude verses mass flow must be performed before hand.

Art Unit: 3651

In regards to claim 17, it is obvious that the bulk density of the powder within Semenenko '152 hopper can be increased without evacuating the flow path.

In regards to claims 21 and 22, Semenenko '152 discloses all elements per claimed invention. However, it is silent as to the specifics of varying the vibration frequency range between 10Hz –1000KHz. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to vary the vibration frequency between the range of 10Hz-1000KHz to anticipates for the type of powder being discharged, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. In addition, it is obvious that vibrating frequency between 10Hz-100KHz could be provided to Semenenko '152 based of user's design.

10. Claims 4-7, 10, 11, 15, 17, 21, 22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuller et al. 6,488,181.

In regards to claims 4-7, Schuller '181 discloses all elements per claimed invention. However, it is silent as to the specifics of dispensing the powder in the range of about 10 μ g-10mg \pm 10%. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to have dispensed about 10 μ g-10mg \pm 10% of powder from Schuller '181 vibratory dispensing hopper, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re

Aller, 105 USPQ 233. In addition, it is obvious that $10\mu\text{g}$ - $10\text{mg} \pm 10\%$ of powder could be dispensed from Schuller '181 hopper based of user's design.

In regards to claims 10, 11, and 15, Schuller '181 discloses providing input signals to vary the vibration frequency and amplitude of the hopper according to the type of powder formulation held therein. However, it is silent as to the specifics of deriving said signals from the evaluation of observed frequency space to render frequency distribution data of the mass flow analysis of the dry powder formulation.

Nevertheless, it is obvious well known that in order to provide proper input signals to correctly vary the frequency and amplitude of the vibratory hopper according to the type of powder held therein, analysis of frequency/amplitude verses mass flow must be performed before hand.

In regards to claim 17, it is obvious that the bulk density of the powder within Schuller '181 hopper can be increased without evacuating the flow path.

In regards to claims 21 and 22, Schuller '181 discloses all elements per claimed invention. However, it is silent as to the specifics of varying the vibration frequency range between 10Hz – 1000KHz . Nevertheless, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to vary the vibration frequency between the range of 10Hz - 1000KHz to anticipates for the type of powder being discharged, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. In addition, it is obvious that vibrating

Art Unit: 3651

frequency between 10Hz-100KHz could be provided to Schuller '181 based of user's design.

11. Claims 4-7, 10, 11, 15, 17, 21, 22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkas et al. 6,805,175.

In regards to claims 4-7, Pinkas '175 discloses all elements per-claimed invention. However, it is silent as to the specifics of dispensing the powder in the range of about $10\mu\text{g}$ -10mg $\pm 10\%$. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to have dispensed about $10\mu\text{g}$ -10mg $\pm 10\%$ of powder from Pinkas '175 vibratory dispensing hopper, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. In addition, it is obvious that $10\mu\text{g}$ -10mg $\pm 10\%$ of powder could be dispensed from Pinkas '175 hopper based of user's design.

In regards to claims 10, 11, and 15, Pinkas '175 discloses providing input signals to vary the vibration frequency and amplitude of the hopper according to the type of powder formulation held therein. However, it is silent as to the specifics of deriving said signals from the evaluation of observed frequency space to render frequency distribution data of the mass flow analysis of the dry powder formulation.

Nevertheless, it is obvious well known that in order to provide proper input signals to correctly vary the frequency and amplitude of the vibratory hopper according to the type of powder held therein, analysis of frequency/amplitude verses mass flow must be performed before hand.

In regards to claim 17, it is obvious that the bulk density of the powder within Pinkas '175 hopper can be increased without evacuating the flow path.

In regards to claims 21 and 22, Pinkas '175 discloses all elements per claimed invention. However, it is silent as to the specifics of varying the vibration frequency range between 10Hz –1000KHz. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to vary the vibration frequency between the range of 10Hz-1000KHz to anticipates for the type of powder being discharged, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. In addition, it is obvious that vibrating frequency between 10Hz-100KHz could be provided to Pinkas '175 based of user's design.

Conclusion

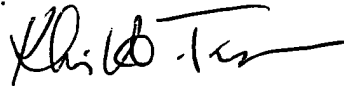
12. Additional references made of record and not relied upon are considered to be of interest to applicant's disclosure: see attached USPTO Form 892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khoi H Tran whose telephone number is (703) 308-1113. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Ellis can be reached on (703) 308-1113. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khoi H Tran
Primary Examiner
Art Unit 3651

KHT
02/224/2005